

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 3

CX/FICS 07/16/3

September 2007

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION  
AND CERTIFICATION SYSTEMS**

**Sixteenth Session**

**Surfer's Paradise, Queensland, Australia, 26-30 November, 2007**

**PROPOSED DRAFT APPENDIX TO THE CODEX GUIDELINES ON THE JUDGEMENT  
OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD  
INSPECTION AND CERTIFICATION SYSTEMS**

**(At Step 3)**

**(Prepared by a physical working group which met in Brussels, Belgium 9-12 July 2007<sup>1</sup>)**

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 2 November 2007** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: [codex.contact@daff.gov.au](mailto:codex.contact@daff.gov.au)), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: [codex@fao.org](mailto:codex@fao.org)).

## BACKGROUND

1. At its 12<sup>th</sup> Session CCFICS recommended<sup>2</sup>, and the Commission agreed, that new work be undertaken on proposed draft appendices to the adopted *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL - 53/2003). The Committee's Project Document stated that the following main aspects would be covered in the proposed new work.

- Assessing which measures are to be the subject of an equivalence determination;

<sup>1</sup> Australia, Argentina, Belgium, Brazil, Canada, China, Czech Republic, European Community, France, Italy, Japan, Latvia, Malaysia, Mexico, Netherlands, New Zealand, Panama, Philippines, Poland, Portugal, Thailand, South Africa and the United States of America

<sup>2</sup> ALINORM 04/27/30, para 88(a).

- Documentation for evaluation of submissions of requests for equivalence determinations;
- Terms for on-site visits by importing country authorities undertaking a determination of equivalence;
- Determining an “objective basis of comparison”;
- More detail on the process of judging equivalence; and
- Information relating to technical assistance to be provided by importing countries to exporting countries;

2. Over the next two Sessions, CCFICS considered Discussion Papers<sup>3</sup> prepared by the United States with the assistance of a working group. While, originally, the Committee proposed that work on the various appendices should be carried out in a step-wise fashion, at its 14<sup>th</sup> Session CCFICS observed that certain elements of each of the five proposed appendices were needed to understand the others and that it might be better, both for logic flow and to avoid duplication, to develop a single combined appendix.

3. CCFICS, at its 15<sup>th</sup> (2006) Session<sup>4</sup>, noted the in-depth discussions that had occurred at the June, 2006 physical Working Group meeting, and the significant changes that had been made in the text of the appendix. Whereas some delegations were generally pleased with the text, most still had concerns regarding its format, scope, relationship with the parent document, clarity and utility as guidance both for developing and developed countries. The Committee collected general and specific comments on the document. These comments focused on:

- Assuring that the guidance contained in the appendix supplemented and was linked to the flow of the parent document, but did not paraphrase it.
- Clarifying whether and how the guidance pertained to judging the equivalence of individual sanitary measures, groups of measures or systems made up of measures.
- Providing practical guidance for countries to consider in weighing the costs of pursuing equivalence versus another means for achieving the intended benefits of an equivalence determination.
- Assuring that the section on Objective Basis of Comparison was sufficiently developed, with real examples, to provide useful guidance for countries.
- Providing guidance on the utility of experience, knowledge and confidence in contributing to a determination of equivalence of sanitary measures.

4. The Committee acknowledged that the scope of the appendix may need to be narrowed to progress the document. The committee re-established the physical Working Group and asked that it: 1) consider all country comments received and provided at the 15<sup>th</sup> Session of CCFICS; 2) broaden the “upfront” contextual portion of the appendix as laying the foundation upon which the rest of the guidance is based; 3) consider the parent document’s reference to tiers of measures in the context of experience, knowledge, and confidence and its linkage to qualitative and quantitative measures; and, 4) provide good examples in regard to the Objective Basis of Comparison. CCFICS also noted that the Appendix should not be repetitious of the parent text and should add significant value and explanation to the parent document. The United States agreed to prepare a new version of the appendix document prior to the meeting of the Working Group in Brussels in July, 2007.

5. At the kind invitation of the European Community, the Working Group met in Brussels, Belgium from 9-12 July 2007. The Working Group was chaired by Mr Greg Read, in his capacity as the Chair of CCFICS. A list of Working Group participants is given in Attachment 2.

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<sup>3</sup> CX/FICS 04/13/3, CX/FICS 05/14/3

<sup>4</sup> ALINORM 07/30/30, paragraphs 41-59.

6. The Working Group considered a substantially revised document that contained major sections on “preliminary considerations relating to undertaking an equivalence determination” and “guidance on undertaking an equivalence determination”. The initial section focused on factors and preparatory steps that countries should take into account when considering an equivalence determination. The latter section focused on providing additional guidance on specific provisions of the main document including those relating to “experience, knowledge and confidence”, the “objective basis of comparison”, information and documentation contained in submissions for an equivalence determination, and detail on the process of judging equivalence.

7. The Working Group noted that while the focus of this document was to provide additional guidance with respect to the provisions of the main Guideline, certain sections of the *Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999) were pertinent. Of specific note were those sections relating to setting priorities before entering into an equivalence determination and relating to the type of information likely to be considered in development of submissions for evaluation of a request for an equivalence determination. These sections were taken into account and referenced.

8. Extensive discussion occurred on the subject of scope and “scoping an equivalence determination”.

9. The Working Group agreed that the scope of the Appendix needed to stay within the Guideline; that is, the scope of document deals with sanitary measures and does not extend into other components of a food control system (e.g., aspects relating to composition or labelling).

10. The Working Group also discussed at some length the subject of equivalence in the context of specific measures versus systems (which would normally be comprised of many measures or groups of measures). Noting that equivalence determinations must be viewed on a case-by-case basis, the Working Group considered the broad spectrum of circumstances that might result in a request for an equivalence determination. Ultimately the Working Group agreed that the scope of the appendix, like the parent document, is on measures, not systems, while recognizing that measures are embedded within a system. The Working Group noted, however, the value that experience, knowledge, and confidence, and the use of side-by-side comparisons can have in assisting with determining the scope of an equivalence determination, including assistance in reducing the number of measures for which an equivalence determination would be sought. Recognizing the importance of scoping, the Working Group incorporated a section on “scoping the equivalence determination” as the first section in that part of the Appendix dealing with “Guidance on Undertaking an Equivalence Determination”.

11. Reflecting country comments and discussion at the 15<sup>th</sup> (2006) Session, the Working Group agreed to incorporate a section on preliminary considerations relating to undertaking an equivalence determination. This section encompasses factors that may facilitate an equivalence determination, such as experience/knowledge/confidence the importing country has with the exporting country’s food control system, prior history of food trade, or having access to necessary resources including scientific and technical capabilities. Similarly, the Working Group agreed to incorporate a section on “preparatory steps to undertaking an equivalence determination” which includes such items as: considering the benefits and cost/resources implications of an equivalence determination in comparison to other arrangements that meet the same outcomes; assuring that both the importing and exporting countries have access to the necessary scientific and technical resources to carry out the determination; and, developing a clear plan that contains objectives, milestones, timelines and expected outcomes.

12. The Working Group discussed the subject of additional guidance on using an “Objective Basis of Comparison” (OBC), particularly the appropriateness of including examples of OBC’s. While the Working Group incorporated the concept of formal (explicit) versus informal (implicit) OBCs and retained the concept of quantitative and qualitative OBCs, there were mixed views on whether the use of examples would add value. The Working Group ultimately agreed to not include examples at this stage, recognizing that examples may tend to constrain flexibility in utilizing OBCs.

13. The Working Group retained with revisions sections on “experience, knowledge and confidence”, “information and documentation contained in submissions for evaluation of a request for an equivalence determination”, and “details on the judgement of equivalence” that had been in the version of the text considered by the last Session of CCFICS (CX/FICS 06/15/4).

14. Additionally, the Working Group agreed to retain the section on “Technical Assistance”, focusing on those areas where technical assistance would be most appropriate with respect to an equivalence determination.

#### **RECOMMENDATION**

15. The Committee is invited to consider the attached proposed draft appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (Attachment 1) with a view towards its further progression in the Codex Step Procedure.

## ADDITIONAL GUIDANCE TO ASSIST EXPORTING AND IMPORTING COUNTRIES IN UNDERTAKING AN EQUIVALENCE DETERMINATION OF SANITARY MEASURES

1. This appendix relates to sanitary measures associated with a food inspection and certification system and clarifies certain aspects of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003).

### PRELIMINARY CONSIDERATIONS RELATING TO UNDERTAKING AN EQUIVALENCE DETERMINATION

2. There is a broad spectrum of circumstances where an exporting country may wish to seek an equivalence determination with an importing country. While each circumstance will likely need to be considered on a case-by-case basis, it can vary from seeking equivalence for a set of sanitary measures making up a food control system associated with a certain type of food or group of foods (e.g. dairy products) to seeking equivalence for a sanitary measure (e.g. analytical method).

3. Factors that may facilitate the equivalence determination of sanitary measures could include the following:

- a) The experience, knowledge and confidence the importing country has with the exporting country's food control system (see paragraphs 9 to 17 below);
- b) The prior history in food trade between the importing and exporting countries;
- c) The level of compliance of the exporting country's food products with the importing country's requirements;
- d) The level of cooperation that exists between the food safety competent authorities of the importing and exporting countries;
- e) The extent to which importing and exporting countries' food control systems are similar (e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs);
- f) Being well prepared to undertake an equivalence determination, including that the importing and exporting countries have access to the necessary resources such as the scientific and technical capabilities;
- g) Consideration of the relevance of any previous equivalence determinations made by the importing country.

### Preparatory steps to undertaking an equivalence determination

4. Preparatory steps, that should be considered include:

- a) Considering the benefits and cost/resource implications of an equivalence determination in comparison to other arrangements that meet the same outcome;
- b) Taking into account the considerations relating to setting priorities contained in Section 5, "Considerations before entering into bilateral or multilateral discussions", of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999);
- c) Assuring that the importing and exporting countries have access to the necessary scientific and technical resources to carry out an equivalence determination, recognizing that a proposal for equivalence will need to be well considered and thoroughly documented;

- d) Where practicable the importing and exporting country should at an early stage in the equivalence determination process develop a clear plan containing, objectives, milestones, timelines and expected outcomes.

## **GUIDANCE ON UNDERTAKING AN EQUIVALENCE DETERMINATION**

### **Scoping the equivalence determination**

5. The exporting country should appropriately scope the request for an equivalence determination by identifying the sanitary measures and food commodity combination to be submitted for consideration.
6. The exporting country must decide on which of the importing country's measures it will meet by compliance and for which measures it will seek equivalence.
7. In some situations it will be clear as to the specific measure or group of measures that are the subject of the equivalence determination.
8. In other situations the scope of the equivalence determination is not clear and categorization of sanitary measures as referred to in paragraphs 13 and 14 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)* may assist in determining the scope of the equivalence determination. Specifically categorisation assists with organising and carrying out side-by-side comparisons of sanitary measures and identifying which measures will be the subject of the equivalence determination

### **Experience, knowledge and confidence**

9. The following section expands on information presented in paragraph 10-12 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)* and provides additional guidance relating to what constitutes experience, knowledge and confidence.
10. Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between the two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved in the equivalence determination. Other factors may include:
  - a) general knowledge of the exporting country's food control system as demonstrated by, among other things, a side by side comparison;
  - b) results of audits/inspections/field examinations by the importing country, exporting country, other countries, or other officially recognized third party organizations;
  - c) knowledge of the exporting country's application and implementation of the risk analysis principles in their food control system;
  - d) port of entry inspection and test results, including records of import rejections and alerts by the importing country as well as from other trading partners;
  - e) agreements the importing country may already have with the exporting country, including equivalence agreements;
  - f) bilateral or multilateral agreements on recognition of equivalence with other countries;
  - g) impact on food control systems as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies;
  - h) contingency plans for containing and mitigating the effects of food safety emergencies;
  - i) food borne disease surveillance data associated with the food product;
  - j) the degree to which industry in the exporting country uses appropriate processing controls;
  - k) adequacy of the exporting country's legislation and, as appropriate, quality control systems;

- l) level/form of oversight of the food production system by the exporting country's certifying authority;
- m) acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country;
- n) any specific export control system in operation.

14. The importing country can apply such experience, knowledge and confidence at any point throughout the equivalence determination process.

15. Experience, knowledge and confidence may assist in facilitating familiarity with the information provided by the exporting country and therefore reduce the resources required to form a judgement of equivalence of the measures proposed.

16. Situations where experience, knowledge and confidence can assist include:

- a) in making a decision as to whether and how to proceed with a request for a judgement of equivalence;
- b) in setting priorities, as may be appropriate (reference should also be made to Section 5, "Considerations Before Entering into Bilateral or Multilateral Discussions", of the *Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999));
- c) in informing the process of comparing the exporting country's relevant sanitary measures with the importing country's sanitary measures;
- d) in reducing the number of sanitary measures that are to be the subject of a detailed examination;
- e) In reducing the extent of the scientific evidence required to determine equivalence.

17. In applying experience, knowledge and confidence to a determination of equivalence, transparency is essential so that the use and application of this information is clear to all parties.

### **Objective Basis of Comparison**

18. The objective basis of comparison (OBC) is a tool that can be formally (explicit) or informally (implicit) expressed by the importing country when undertaking an equivalence determination.

19. An objective basis of comparison may be quantitative and/or qualitative in nature. The objective basis for comparison of sanitary measures categorized as "infrastructure" is likely to be of a qualitative nature, e.g. the ability of food control legislation to achieve broad food safety goals. The objective basis of comparison of sanitary measures categorised as "specific requirements" is likely to be quantitative in nature, e.g. a comparison of levels of hazard control achieved by the measure. The objective basis of comparison of sanitary measures categorized as "programme" is likely to contain a mixture of qualitative and quantitative elements e.g. correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

20. The following paragraph expands on information presented in paragraphs 15 and 16 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003) and provides additional guidance relating to what constitutes the development of a formal objective basis of comparison. Depending on the scope of the equivalence determination there may be more than one OBC.

21. When developing OBC(s) the importing country should gather and assess scientific data and other information<sup>1</sup> and enter into a dialogue with the exporting country to seek agreement on the OBC(s). The

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<sup>1</sup> In the context of this appendix data is taken to mean both quantitative and qualitative data and other information

OBC development process should, as appropriate:

- a) Ensure sufficient data to provide valid support for conclusions;
- b) Ensure the adequacy and accuracy of the data;
- c) Utilize risk assessments, as available; and
- d) Ensure sufficient knowledge and technical expertise of the subject matter experts

### **Information and Documentation Contained in Submissions for Evaluation of a Request for an Equivalence Determination**

22. The following section provides additional guidance on what information should be contained in a country's submission for an equivalence determination.

23. Paragraphs 16-20 of Section 7, "Consultative process for equivalence agreements", of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL-34-1999)* provide guidance and the type of information that may need to be included in a submissions package.

24. Before forwarding a submission package to the importing country, an exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned, and have made appropriate contact with its counterpart in the importing country.

25. The submission package should specify the measure(s) for which equivalence is sought.

26. It may often be the case that a submission package is done in steps. For example the exporting country provides the measures for which an equivalence determination is sought. The importing country then provides the OBC if required.

27. Depending upon the nature of the OBC (see paragraph 18 of this appendix), exporting countries should provide the following information and data:

- a) For a qualitative OBC, references to pertinent scientific information should be provided. The submission package should also contain a written analysis by the exporting country's subject matter experts explaining how they arrived at their conclusion that the exporting country's measures are equivalent to the importing country's measures.
- b) For a quantitative OBC, the submission package should include: the data used to assess the equivalence of the measure; the methodology used to obtain the data; the methodology used to assess the data including, as appropriate, the risk assessment models employed, and the assumptions made and the nature and extent of uncertainty of the findings. The submission package should also contain a written analysis that clearly shows how the exporting country arrived at the conclusion that its measure(s) are equivalent to the importing country's measure(s).



### **Details on Judgement of Equivalence**

28. The following expands on Sections 7 and 8 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)*.

29. In the process of judging equivalence the importing country should focus on those measures or groups of measures which the exporting country and importing country have mutually agreed will be the subject of the equivalence determination.

30. Ongoing communication between the importing and exporting countries may assist with the judgement of equivalence process to, among other things, clarify technical points and respond to the need for additional information.

31. Importing countries may undertake to judge equivalence based only on a review of the data and information. Some countries may also utilise on-site visits to clarify information provided by the exporting country. Subject matter experts in the importing may also be utilised especially in reviewing the conclusions of the exporting country.

32. At any point in the process, an importing country in consultation with the exporting country should be able to stop the process when evidence exists that equivalence is not possible.

33. A decision regarding the judgement of equivalence based on available information taking into account experience, knowledge and confidence can be made at any point in the process including:

- a) At initial contact by the exporting country;
- b) Following review of the submission package by the importing country, including the opinions of subject experts where necessary;
- c) Following an assessment based on an objective basis of comparison.
- d) Following an assessment of the information gathered during onsite visits by the importing country;
- e) Following the resolution of outstanding issues.

34. As agreed to between the importing and exporting countries, the importing country should provide to the exporting country a written report as to whether or not equivalence has been found. Where equivalence is not found, the reasoning for this should be given to the exporting country and should be included in the written report with suggestions for solutions where possible.

### **Use of On-site visits**

35. To complement the documentary review by the importing country, the use of on-site visits may be beneficial in clarifying information provided by the exporting country. The rationale for on-site visits related to the determination of equivalence may include:

- a) To help clarify information provided by the exporting country relevant to its sanitary measures subject to the equivalence determination;
- b) To gather additional information on the exporting country's proposed measures that may be required by the importing country to undertake a judgement of equivalence;
- c) To improve knowledge and confidence in the exporting country's food control system.

36. In preparing for an on-site visit, both the importing and exporting country should consider:
- a. Limiting the scope of on-site visits to the food product or group of food products and the associated sanitary measures that are the subject of the equivalence determination
  - b. The development of a protocol for the on-site visit.

### **Provision of Technical Assistance**

37. The following expands on paragraph 7 (n) of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003), the principle relating to technical assistance, and provides additional guidance relating to the provision of technical assistance. It is possible that technical assistance may be needed by importing and exporting countries in carrying out equivalence determinations.

38. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:

- Technical assistance is not a mandatory pre-requisite by either party in undertaking a determination of equivalence.
- Appropriate areas for technical assistance associated with an equivalence determination could include:
  - assistance in evaluating which measures would be the subject of an equivalence determination;
  - assistance with the preparation of documentation, including the submittal package;
  - assistance in undertaking necessary risk assessments;
  - assistance with data analysis;
  - assistance in assessing whether measures meet the importing country's stated objective basis of comparison; and
  - Exchange of technical expertise between the importing and exporting countries.

## Attachment 2

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